

REMARKS

Restriction has been imposed among four groups of claimed subject matter:

- I. Claims 1-16 drawn to a method of improving sexual performance in a male.
- II. Claims 17-31 drawn to a method of increasing the libido of men.
- III. Claims 32-50 drawn to a method of improving the efficacy of a pharmaceutical useful for treating erectile dysfunction in a male.
- IV. Claims 51-56 drawn to a pharmaceutical kit comprising specified components herein.

Applicants elect, with traverse, to prosecute the subject matter of Group "III" as found in Claims 32-50. Claims 34 and 50 have been canceled. Claim 50 has been rewritten in independent form as claim 100, and dependent claims 57-99 have been added. Accordingly, claims 32, 33, 35-49, and 57-100 are at issue in this application.

Claim 49 was objected to for minor informalities. The claim has been amended to better define the invention. Applicants request reconsideration and withdrawal of this rejection in view of the amended claim.

Claim 50 was objected to under 37 CFR §1.75(c), as being of improper dependent form for failing to limit the subject matter of a previous claim. Claim 50 has been cancelled and rewritten in independent form as claim 100. Applicants request reconsideration and withdrawal of this rejection in view of the rewritten claim.

Claims 35, 36, 38, 39, 41-46, 48 and 50 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. The claims have been amended to better define the invention. Applicants request reconsideration and withdrawal of this rejection in view of the amended claims.

Support for the amendments made to claim 32 is found on at least page 11, line 24, to page 12, line 1. OK

Support for the amendment made to claim 36 is found on at least page 48, line 18. ✓

Support for the amendments made to claims 41 and 42 are found on at least page 14, lines 5-6, of the specification. ✓

Support for the amendment made to claim 43 is found on at least page 13, lines 4-5, of the specification.

Support for the amendment made to claim 44 is found on at least page 13, lines 4-5, and on page 14, lines 5-6, of the specification.

Support for the amendment made to claim 48 is found on at least page 18, lines 13-16, of the specification.

Support for new claim 57 is found on at least page 52, line 18, of the specification.

Support for new claim 58 is found on at least page 17, lines 20-24, of the specification.

Support for new claim 59 is found on at least page 22, lines 11-14, of the specification.

Support for new claim 60 is found on at least page 35, line 11, of the specification.

Support for new claim 61 is found on at least page 35, line 11, of the specification.

Support for new claim 62 is found on at least page 19, line 6, of the specification.

Support for new claim 63 is found on at least page 19, lines 5-6, of the specification.

Support for new claim 64 is found on at least page 19, lines 6-7, of the specification.

Support for new claims 65-67 is found on at least page 14, lines 5-6, of the specification.

Support for new claims 68 and 69 is found on at least page 14, line 6, of the specification.

Support for new claims 70 and 71 is found on at least page 14, line 6, of the specification.

Support for new claims 72 and 73 is found on at least page 14, lines 7, of the specification.

Support for new claim 74 is found on at least page 14, lines 3-7, of the specification.

Support for new claims 75-77 is found on at least page 14, lines 5-6, of the specification.

Support for new claims 78 and 79 is found on at least page 14, lines 6, of the specification.

Support for new claims 80 and 81 is found on at least page 14, lines 6-7, of the specification.

Support for new claims 82 and 83 is found on at least page 14, line 7, of the specification.

Support for new claim 84 is found on at least page 36, lines 9-11, of the specification.

Support for new claim 85 is found on at least page 39, lines 13-14, of the specification.

Support for new claim 86 is found on at least page 39, lines 15-16, of the specification.

Support for new claim 87 is found on at least page 46, lines 15-16, of the specification.

Support for new claim 88 is found on at least page 47, lines 22-23, of the specification.

Support for new claims 89 and 90 is found on at least page 47, lines 24-26, of the specification.

Support for new claim 91 is found on at least page 53, line 25, to page 54, line 1, of the specification.

Support for new claim 92 is found on at least page 53, line 25, to page 54, line 1; page 54, lines 7-10, of the specification.

Support for new claim 93 is found on at least page 51, lines 4-6, of the specification.

Support for new claim 94 is found on at least page 53, line 13, of the specification.

Support for new claim 95 is found on at least page 12, lines 1-2, of the specification.

Support for new claim 96 is found on at least page 12, lines 1-2, of the specification.

Support for new claim 97 is found on at least page 53, line 25, to page 54, line 1; page 54, lines 7-10, of the specification.

Support for new claim 98 is found on at least page 54, lines 17-19, of the specification.

Support for new claim 99 is found on at least page 54, lines 19-20, of the specification.

Claims 32-50 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Omar (U.S. Patent No. 5,730,987) and Mak *et al.* (WO 99/24041-A1) and Moreland *et al.* (Life Sciences 1998, 62(2), 309-318) in view of Allen (WO 96/27372-A1).

Applicants disagree and traverse this rejection. Omar, Mak *et al.* and Moreland *et al.* in view of Allen do not teach or suggest the claimed invention. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. (MPEP 2143.01 citing In re Mills, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990)).

As it now stands before the Patent Office, claim 32 claims a method of improving the efficacy of a pharmaceutical useful for the treating erectile dysfunction in a male subject, comprising percutaneously administering a pharmaceutically effective amount of a steroid in the testosterone synthetic pathway to the subject in a composition comprising at least one of a C1-C4 alcohol, the steroid, a thickener, and a penetration enhancer; and administering the pharmaceutical to the subject. Claim 100 claims a method for improving the efficacy of a pharmaceutical useful for treating erectile dysfunction in a male subject, comprising percutaneously administering a pharmaceutically effective amount of a steroid in the testosterone synthetic pathway to the subject in a composition comprising at least one of a C1-C4 alcohol, the steroid, a thickener, and a penetration enhancer; and administering the pharmaceutical to the subject; wherein the subject achieves hormonal steady state levels of testosterone. Claims 32, 33, 35-49, and 57-99 are dependent from claim 32.

Omar teaches oral administration of a powdered composition of lyophilized roe and powdered extract of *Gingo biloba*. It is also mentions that testosterone may be administered by injection, orally or by buccal tablets for hypogonadism. Omar does not teach or suggest improving the efficacy of a pharmaceutical administered to a male subject useful for treating erectile dysfunction by percutaneously administering a steroid in the testosterone pathway.

Mak *et al.* teach transdermal and topical delivery of testosterone, a C1-C4 alcohol and a penetration-enhancing agent. However, Mak *et al.* do not teach or suggest a method of improving the efficacy of a pharmaceutical administered to a male subject useful for treating erectile dysfunction by percutaneously administering a steroid in the testosterone pathway.

Moreland *et al.* teach oral administration of sildenafil for the treatment of male erectile dysfunction. Moreland *et al.* do not teach or suggest improving the efficacy of a pharmaceutical administered to a male subject useful for treating erectile dysfunction by percutaneously administering a steroid in the testosterone pathway.

Allen teaches a water-based topical cream containing the vasodilator nitroglycerin (which is not a hormone that plays a role in erections) for the treatment of male erectile dysfunction. Allen does not teach or suggest improving the efficacy of a pharmaceutical administered to a male subject useful for treating erectile dysfunction by percutaneously administering a steroid in the testosterone pathway.

Furthermore, there is no motivation to combine the cited references. The Office Action states that "It would have been obvious to a person of ordinary skill in the art. . . to

employ the particular steroid, testosterone, C1-C4 alcohol, and the particular penetration enhancer, C8-C22 fatty acid and isopropyl myristate in a method for improving the efficacy of the composition herein useful for treating erectile dysfunction in a male who may be an eugonadal, and to further add the phosphodiesterase type 5 inhibitor, sildenafil or yohimbine HCl to the composition, and optimize the effective amounts of active ingredients in the composition.” However, the Office Action does not cite any reference showing or suggesting the interchangeability of these elements.

In making this unsupported statement of interchangeability, the Office Action is attempting to shift the burden of proof of unobviousness to the Applicants. In the case of In re Grabiak (226 USPQ 870 (CAFC 1985) at 872) the Court of Appeals for the Federal Circuit held that the USPTO’s rejection of claims toward a herbicide safener invention was improper because the USPTO cited no pertinent reference showing or suggesting to one of ordinary skill in the art the change of a thioester for an ester group in the herbicide safener invention.

Additionally, the applicants respectfully submit that the teaching of In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (CCPA 1980) has been misapplied in determining the obviousness of the present invention.

The applicants contend that the appropriate standard to determine obviousness in this case is not found in In re Kerkhoven. The decision in In re Kerkhoven was based upon prior art teachings and the applicant’s own admissions. The court noted that the Examiner stated during the proceedings that:

“th[e] process [of the invention] would be suggested by the teachings in Tofflemire [a cited prior art reference] and appellant’s admission in the sentence bridging pages 27 and 28 of his brief that ‘given the long standing practice of spray drying with a multiplicity of nozzles, the possibility of introducing separate streams to any or all of these separate nozzles would be obvious to anyone of ordinary skill in the art.’” Id. at 849.

It was also noted that the applicant admitted before the board that a prior art reference “makes detergent compositions by spray drying two detergent slurries of different chemical composition simultaneously in a tower.” Id. at 850. The applicant also admitted “that simultaneous spray-drying of two detergent slurries was known.” Id.

The present situation is distinguishable from In re Kerkhoven in many respects and is more analogous to In re Geiger, 815 F.2d 686, 2 U.S.P.Q.2d 1276 (Fed. Cir. 1987). In In re

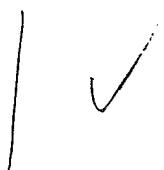
Geiger the prior art did not suggest combining references and the applicant made no admissions concerning the prior art. Also, the three components of the invention of In re Geiger had been described in the prior art individually or in partial combination.

In In re Geiger, the board was reversed when it held that: “based upon prior art and the fact that each of the three components of the composition used in the claimed method is conventionally employed in the art for treating cooling water systems...,[it] would have been prima facie obvious within the meaning of 35 U.S.C. § 103, to employ these components in combination for their known function....” Id. at 687.

The Federal Circuit rejected this conclusion and stated that “the PTO failed to establish a prima facie case of obviousness.” The court stated that “obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention absent some teaching, suggestion or incentive supporting the combination.” Id. at 688 (citing ACS Hospital Systems, Inc. v. Montefiore Hospitals, 732 F.2d 1572, 1577, 221 U.S.P.Q. 929, 933 (Fed. Cir, 1984).

The court went further and stated that “[a]t best, in view of [the cited references], one skilled in the art might find it obvious to try various combinations of these known...agents. However, this is not the standard of 35 U.S.C. § 103.” 815 F.2d 688, (Fed. Cir. 1987) (citations omitted).

In In re Geiger the Federal Circuit found that although the prior art disclosed the separate components of the claimed new composition, and for the same general use, a prima facie case was not established “absent some teaching, suggestion or incentive supporting the combination.” In re Geiger (815 F.2d. 686, 688, 2 USPQ2d at 1278.



In the 35 U.S.C. §103(a) rejection of the present claims, the Office Action has cited no pertinent reference showing or suggesting to one of ordinary skill in the art the interchangeability of elements in the present claims. The 35 U.S.C. § 103(a) rejection is therefore improper. Further claims 33-49 depend on the patentability of claim 32. If claim 32 is patentable, then so to are claims 33-49, regardless of whether other references teach their subject matter. Reconsideration and withdrawal of this 35 U.S.C. §103(a) rejection is requested.

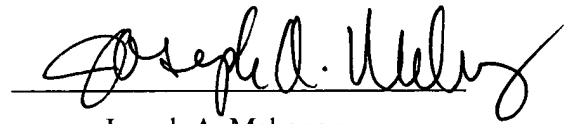
With entry of the above Amendment and in view of the foregoing remarks, it is respectfully submitted that claims 32, 33, 35-49, and 57-100 are in condition for allowance. Also submitted herein, on a separate page titled “Version with Marking to Show Changes

Made to the Claims," is a marked up copy of prior pending claims 32, 35, 36, 38, 39, 41-46, 48, and 49. This page shows the changes made to prior pending claims 32, 35, 36, 38, 39, 41-46, 48, and 49 and how claims 32, 35, 36, 38, 39, 41-46, 48, and 49, as amended, now stand before the Patent Office. It is respectfully submitted in view of the foregoing Amendment and Remarks that all of the objections and rejection in the Office Action dated April 24, 2001 have been overcome and should be withdrawn. Accordingly, reconsideration and withdrawal of the outstanding rejections and allowance of claims 32, 33, 35-49, and 57-100 is respectfully solicited. Applicant respectfully requests early and favorable notification to that effect.

Respectfully submitted,

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